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ONE HUNDRED SEVENTH CONGRESS

# Congress of the United States

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August 28, 2001

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Dr. Ruth Kirschstein  
Acting Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Kirschstein:

On August 9, 2001, President Bush announced that he would allow federal funding on stem cell lines derived from embryos before his announcement. In his remarks, he said: "[M]ore than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research." According to press accounts, President Bush got this number from NIH scientists who briefed him on August 2, 2001.<sup>1</sup>

Yesterday, NIH made public the names and locations of the entities that reported to NIH that they have derived embryonic stem cells that meet the President's criteria. Today's *Washington Post* reported that as many as one third of those 64 stem cell lines may not be viable for research because they are too young and too fragile.<sup>2</sup>

The announcement that there are over 60 stem cell lines that already exist took many scientists in the field by surprise.<sup>3</sup> The scientific literature contains information on approximately 10 stem cell lines.<sup>4</sup> As I am sure you know, there is great concern in the scientific

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<sup>1</sup> *How Bush Got There*, Time, 17 (Aug. 20, 2001).

<sup>2</sup> *Stem Cell Colonies' Viability Unproven*, Washington Post (Aug. 28, 2001).

<sup>3</sup> See *Viability of Stem Cell Plan Doubted; Bush Policy Could Limit Research*, Washington Post (Aug. 20, 2001). See also Dr. Lawrence Goldstein, *A Convergence of Science, Politics and Ethics*, San Diego Union-Tribune (Aug. 19, 2001). See also *President Bush's Stem Cell Policy*, A Statement of the American Association for the Advancement of Science (Aug. 17, 2001).

<sup>4</sup> Dr. Lawrence Goldstein, *A Convergence of Science, Politics and Ethics*, San Diego Union-Tribune (Aug. 19, 2001).

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community that these existing stem cell lines may be inadequate either because they may not represent sufficient genetic diversity or they may not be genuinely accessible to researchers. Press accounts suggest that because the human cells in these lines may have been grown with mouse cells, these lines may not be usable to create actual therapies.<sup>5</sup> In order to allay these concerns and to ensure that valuable research is not impeded, we need to know more about the stem cell lines that the NIH staff described to the President. I ask that you provide the following information. Please provide a distinct response for each cell line. If you do not have the requested information, please state that as your answer:

- 1 Identify the name of the developer of each cell line.
  2. What date did the line originate?
  3. Identify the race and any other known genetic information of the donors of the embryonic cells.
  4. Describe how the line was derived.
  5. Describe the method by which the line was cultured. Were any animal cells used to create or sustain the line?
  6. Is the line virus-free? What method was used to determine whether the line was virus-free?
  - 7 Describe any known genetic defects and what method was used to determine whether there are genetic defects.
  - 8 Was the line derived from embryos given through consent procedures that would meet the guidelines proposed by NIH?
  9. Describe the protocol used to demonstrate that the cells are, in fact, stem cells.
  10. Identify any peer-reviewed journal articles that describe or identify the line.
- Has the line been examined by investigators in the NIH intramural research programs or by extramural NIH-supported investigators? Please provide any publications that describe those examinations.
12. Has the line been patented? If NIH does not know if a particular line is patented or not, please include that in the response.

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<sup>5</sup> *Stem Cell Research Faces FDA Hurdle*, Washington Post (Aug. 24, 2001).

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13. If the line is covered by a patent, identify the owner of the patent and describe whether licenses (or other permissions to use the line) to use the line have been issued to researchers not employed or supported by the patent-holder? If NIH does not know if such licenses have been issued, please include that in the response.
14. In the case of each line for which licenses (or other permissions to use the line) have been issued, what royalties, rents, or other payments have been associated with the license? What restrictions (other than payments) have been associated with the license? Does the holder of the patent on the line gain ownership interest in any products developed from that line?
15. In the case of each line for which licenses (or other permissions to use the line) have not been issued, what is known about the willingness of the patent-holder to issue licenses (or other permissions to use the line)? What royalties, rents, payments, or restrictions have patent-holders proposed? What is NIH doing to investigate these legal and financial issues?
16. Are all the questions about the quality and availability of the stem cell lines resolved such that these cells are now available for research?

Please answer these questions by close of business September 11, 2001. If you believe that you will not be able to meet this deadline, please contact me or Tim Westmoreland of my staff at (202) 225-3976 as soon as possible. If you or your staff have any questions regarding this request, please call Sarah Despres or Josh Sharfstein at (202) 225-5420.

Sincerely,

A handwritten signature in dark ink, appearing to read "Henry A. Waxman". The signature is fluid and cursive, with the first name "Henry" being the most prominent part.

Henry A. Waxman  
Ranking Minority Member